Claims 1-4 have been rejected under 35 USC Section 102(b) as allegedly anticipated by Japanese Application No. 11-352411 to Berndt ("Berndt"). Applicant respectfully submits that Berndt does not anticipate or teach the claimed invention.

At Page 3, Lines 20-24 of the Official Action, under point (d), the Examiner states that Berndt discloses "a means for changing the thickness for said container by a known amount (see figure 3, wherein the thickness of the container has changed a known amount, as determined by laser deflection; since the curvature of the deflection has been measured by laser deflection for one sample and one container, the change in the thickness will be known within very close range in all future deflections)."

In Berndt the change in container thickness as a result of the filling with liquid has been determined by means of laser deflection. However, in Berndt, it is important that the spread liquid sample, such as blood, fills the space between the slide and the coverglass only partially; and furthermore, the coverglass is held in a stable position due to an equilibrium state between adhesion forces and counter forces generated as a consequence of coverglass bending.

The "equilibrium state" mentioned in Berndt, i.e. the exact bending of the coverglass, and, therefore, the thickness of the container after filling, depends on two major factors. First, the specific sample volume entered into the container will have an impact on the area of the coverglass that is coming into contact with the liquid sample. The size of this contact area will determine the amount of adhesion force that comes into play. The larger the contact area, the larger the adhesion force. This, in turn, means stronger bending for a larger sample volume. The second factor is the fact that every single coverglass has its own "personality". In other words, every single coverglass shows a specific initial bending prior to coming into contact with liquid sample. Considering these to factors, no two containers will ever show identical bending, or for that matter, identical "change in thickness" due to the filling. Consequently, measuring the bending on one container would not provide information on the actual bending that occurs on a second container.

Applicant further directs the Examiner's attention to the fact that an apparatus according to the present invention provides a material platform for operating a method for determining the volume of individual red blood cells, that is based on changing the

thickness of the container by a small but precisely known amount, after the container has been filled with liquid sample. This is described in the present specification at page 9, lines 5 to 12 as follows:

"In a next step, cuvette (20) is moved further upwards by means of stage (5) by a small, but precisely known distance, h. Moving cuvette (20) upwards against plunger (11) results in a reduction in the optical path length within the cuvette by an amount identical to h. When cuvette (20) has been moved, a new reemerging light intensity, I_2, in the same area is measured, and the result stored in computer (22). The new light intensity, I_2, has a higher value than the first intensity, I_1, because a smaller sample thickness results in less absorption of light within the sample."

In contrast to this aspect of the present invention, Berndt discloses a device for ***preparing*** thin liquid samples for microscopic analysis. In other words, Berndt is aiming at the production of thin layers of liquids, but it does not disclose (and does not require) means for generating small and well-defined ***changes*** in the thickness of the liquid layer that is being generated.

In view of the above considerations, Applicant respectfully submits that the Examiner is incorrect in suggesting that a precise change in container thickness is anticipated by Berndt.

Finally, Applicant respectfully notes that the inventor has collaborated for years in the development of such containers with a German company that is well known for its high-quality precision-molded microfluidic microstructure devices. This company had developed test containers for the inventor that included height-calibration features such as steps in the container height. It was found that the calibration features could not be positioned within container areas of significant height (e.g. > 10 µm) due to the presence of Roleaux-forming red blood cells. Instead, the calibration features had to be positioned within the container where the height was very low (e.g. 5 µm), so that cell-free areas could be found. However, due to the fact that in this case the calibration features had to be produced reproducibly with sub-micrometer precision in height, the cost for producing the containers would have been at an intolerably high level. Consequently, inventor found the use of volume-defined features for calibration within the container as impractical. It should be noted that for application in medical

diagnostics the containers preferably have to be disposables that receive a liquid sample only once, and are then discarded to prevent carry-over artifacts and to prevent exposing medical personnel to potentially contagious clinical materials.

The present invention teaches a surprisingly convenient and practical way to perform a height calibration in cell-free areas of minimum height (e.g. 3 µm to 10 µm) without the need for having volume-defined features in place. This is accomplished by pressing onto a flexible window to achieve a precisely defined reduction in the optical path length (= height). Due to the fact that such containers according to the present invention are read while on the XYZ-stage of an optical reader such as a microscope, the requirement for producing a precisely defined change in height is shifted away from the disposable container towards the reading instrument. In other words, a huge number of simple disposable containers without volume-defined features can be produced at low cost, and the required mechanism of providing a precision change in height rests on a few reading instruments. It should also be noted that most modern microscopes are equipped with computer-controlled high-resolution XYZ-stages anyway, or that it would also be feasible to design dedicated reading instruments similar to a microscope that are equipped with a computer-controlled plunger.

Although the claims have been rejected as anticipated under 35 U.S.C. § 102 on the disclosure of Berndt, it is axiomatic that anticipation under Section 102 requires that the prior art reference disclose every element of the claim. In re King, 801 F.2d 1324, 1326, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986). Thus there must be no differences between the subject matter of the claim and the disclosure of the prior art reference. Stated in another way, the reference must contain within its four corners adequate directions to practice the invention. The corollary of this rule is equally applicable. The absence from the reference of any claimed element negates anticipation. Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565, 1571, 230 U.S.P.Q. 81, 84 (Fed. Cir. 1986).

Here it is clear that Claim 1 and the rejected claims dependent thereon distinctly differ from Berndt. Clearly, Kloster Speedsteel shows that Berndt falls far short of the statutory standard of 35 U.S.C. Section 102. Claims 1-4 are not anticipated by Berndt.

Withdrawal of the instant rejection under Section 102 is therefore respectfully requested.

Applicant notes with appreciation the Examiner's comment that Claims 6-9 have been found to be allowable. In view of the above Remarks, it is believed that the present application in its entirety is in condition for allowance. Early notice thereof is respectfully requested by Applicant.

Respectfully submitted,

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